DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2015

GUANGZHOU WONDFO BIOTECH CO., LTD.
C/O JOE SHIA
BUSINESS DIRECTOR
504 EAST DIAMOND AVE. SUITE F
GAITHERSBURG MD 20878

Re: K150179
Trade/Device Name: CR3 Keyless Split Sample Cup Oxycodone - Cannabinoids
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG, LDJ
Dated: January 23, 2015
Received: January 27, 2015

Dear Mr. Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stayce Beck -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k150179

Device Name
CR3 Keyless Split Sample Cup Oxycodone –Cannabinoids

Indications for Use *(Describe)*
CR3 Keyless Split Sample Cup Oxycodone-Cannabinoids is a rapid test for the qualitative detection of Oxycodone and Cannabinoids in human urine at a cutoff concentration of 100 ng/mL and 50 ng/mL, respectively. The test is the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained. The test is intended for over-the-counter and for prescription use.

The test may yield preliminary positive results even when the prescription drug Oxycodone is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for Oxycodone in urine. The CR3 Keyless Split Sample Cup Oxycodone-Cannabinoids test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1. Date: February 18, 2015

2. Submitter: Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District, Guangzhou, P.R. China 510663

3. Contact person: Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite F
Gaithersburg, MD 20878
Telephone: 240-505-7880
Fax: 301-916-6213
Email:shiajl@yahoo.com

4. Device Name: CR^3 Keyless Split Sample Cup Oxycodone –Cannabinoids

Classification: Class II

Product Code	CFR #	Panel
DJG	21 CFR, 862.3650 Opiate Test System	Toxicology
LDJ	21 CFR, 862.3870 Cannabinoid Test System	Toxicology

5. Predicate Devices: K122904
Wondfo Multi-Drug Urine Test Cup

6. Intended Use:
CR3 Keyless Split Sample Cup Oxycodone-Cannabinoids is a rapid test for the qualitative detection of Oxycodone and Cannabinoids in human urine at a cutoff concentration of 100 ng/mL and 50 ng/mL, respectively. The test is the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained. The test is intended for over-the-counter and for prescription use.

The test may yield preliminary positive results even when the prescription drug Oxycodone is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for Oxycodone in urine. The CR3 Keyless Split Sample Cup Oxycodone-Cannabinoids test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only.

7. Device Description:

The CR3 Keyless Split Sample Cup Oxycodone –Cannabinoids test uses immunochromatographic assays for Oxycodone and Cannabinoids. The test is a lateral flow system for the qualitative detection of oxycodone and cannabinoids in human urine. The test is the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

8. Substantial Equivalence Information

Item	Device	Predicate – K122904
Indication(s) for use	For the qualitative determination of drugs of abuse in human urine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Results	Qualitative	Same
Specimen Type	Human urine	Same
Cut Off Values	Oxycodone: 100ng/ml Cannabinoids: 50ng/ml	Same for Oxycodone and Cannabinoids
Configurations	Cup	Cup, Dipcard
Conditions for Use	Over-the-Counter & Prescription Use	Same

9. Test Principle

The CR3 Keyless Split Sample Cup Oxycodone –Cannabinoids test is a rapid test for the qualitative detection of Oxycodone and Cannabinoids in urine samples and contains lateral flow chromatographic immunoassays for oxycodone and cannabinoids. Each assay uses a mouse monoclonal anti-drug antibody-dye conjugate, fixed drug-protein conjugates, and anti-mouse IgG polyclonal antibodies coated on the test membranes. When the absorbent end of the test is immersed into a urine sample, the urine is absorbed into the device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. At analyte concentrations below the target cut-off, antibody-dye conjugates bind to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored test line that indicates a negative result. When analyte concentration is above the cut-off, analyte molecules bind to the antibody-dye conjugate, preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. No colored band shows in

the test region, indicating a potentially positive result. A band should form in the control region (C) of the device regardless of the presence of drug or metabolite in the sample.

10. Performance Characteristics
    1. Analytical Performance
        a. Precision

        Precision studies were carried out for samples with concentrations of -100% cut-off, -75% cut-off, -50% cut-off, -25% cut-off, at the cut-off, +25% cut-off, +50% cut-off , +75% cut-off and +100% cut-off. For each concentration, tests were performed two runs per day by three operators for 25 days. All sample aliquots were masked and randomized. The results obtained are summarized in the following tables:

A. For Oxycodone (OXY) testing

Result / OXY	-100% cut-off	-75% cut-off	-50% cut-off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
W12410301CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-
W12410302CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-
W12410303CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-

B. For Cannabinoids (THC) testing

Result / THC	-100% cut-off	-75% cut-off	-50% cut- off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
W12410301CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
W12410302CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-
W12410303CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-

        b. Linearity

        Not applicable.

        c. Stability

        The CR3 Keyless Split Sample Cup Oxycodone –Cannabinoids is stable at 4-30^{o}C for 18 months as determined by conducting accelerated and real-time stability testing.

Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

d. Cut-off

Cut-off studies were conducted using a total of 125 oxycodone samples and 125 cannabinoids samples equally distributed at concentrations of -50%, -25%, at the cut-off, +25%, +50% of their respective cut-offs. These samples were tested using three different lots by three different operators. Results were all positive at +25% and +50% cut-off and all negative at -25% and -50% cut-off for both oxycodone and cannabinoids. The following cut-off values for the test devices have been verified.

Test	**Calibrator**	**Cut-off (ng/ml)**
Oxycodone (OXY）	Oxycodone	100
Cannabinoids (THC)	11-nor-Δ9-THC-9-COOH	50

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to urine containing target drugs (oxycodone or cannabinoids) at 25% below and 25% above the cut-off. These urine samples were tested using three batches of the CR3Keyless Split Sample Cup Oxycodone – Cannabinoids by three different operators. Compounds that showed no interference at a concentration of 100μg/mL are summarized below:

Oxycodone

4-Acetamidophenol	Ecgonine methylester	Papaverine
Acetophenetidin	L-Ephedrine	Penicillin-G
N-Acetylprocainamide	Erythromycin	Pentobarbital
Acetylsalicylic acid	β-Estradiol	Perphenazine
Aminopyrine	Estrone-3-sulfate	Phenelzine
Amitryptyline	Ethyl-p-aminobenzoate	Phenobarbital
Amoxicillin	Fenoprofen	L-Phenylephrine
Ampicillin	Furosemide	β-Phenyllethylamine
Ascorbic acid	Gentisic acid	Phenylpropanolamine
D,L-Amphetamine	Hemoglobin	Prednisolone
L-Amphetamine	Hydralazine	Prednisone
Apomorphine	Hydrochlorothiazide	Procaine
Aspartame	Hydrocortisone	D,L-Propanolol
Atropine	O-Hydroxyhippuric acid	D-Propoxyphene
Benzilic acid	3-Hydroxytyramine	D-Pseudoephedrine
Benzoic acid	Ibuprofen	Quinidine

Benzoylecgonine
Benzphetamine
Bilirubin
Caffeine
Chloralhydrate
Chloramphenicol
Chlorothiazide
D,L-Chlolrpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Cocaine hydrochloride
Cortisone
L-Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine hydrochloride
D, L-Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Loperamide
Maprotiline
Meprobamate
Methadone
Methoxyphenamine
(+) 3,4-Methylenedioxyamphetamine
(+)3,4-Methylenedioxymethamphetamine
Morphine-3-β-Dglucuronide
Naloxone
Nalidixic acid
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norethindrone
D-Norpropoxyphene
Noscapine
Oxalic acid
Oxolinic acid
Oxymetazoline
p-Hydroxymethamphetamine
Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin (5-Hydroxytyramine)
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone, 3 Acetate
Tetrahydrocortisone3 (β-Dglucuronide)
Tetrahydrozoline
Thebaine
Thiamine
Thioridazine
D, L-Thyroxine
Tolbutamine
Triamterene
Trifluoperazine
Trimethoprim
D, L-Tryptophan
Tyramine
D, L-Tyrosine
Uric acid
Verapamil
Zomepirac

Cannabinoids

4-Acetamidophenol
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amitryptyline
Amoxicillin
Ampicillin
Ascorbic acid
D,L-Amphetamine
L-Amphetamine
Apomorphine
L-Ephedrine
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
p-Hydroxymethamphetamine
Papaverine
Penicillin-G
Pentobarbital
Perphenazine
Phencyclidin
Phenelzine
Phenobarbital
L-Phenylephrine
β-Phenyllethylamine
Phenylpropanolamine
Prednisolone

Aspartame	Hydrocortisone	Prednisone
Atropine	O-Hydroxyhippuric acid	Procaine
Benzilic acid	3-Hydroxytyramine	D,L-Propanolol
Benzoic acid	Ibuprofen	D-Propoxyphene
Benzoylecgonine	D, L-Isoproterenol	D-Pseudoephedrine
Benzphetamine	Isoxsuprine	Quinidine
Bilirubin	Ketamine	Quinine
Caffeine	Ketoprofen	Ranitidine
Chloralhydrate	Labetalol	Salicylic acid
Chloramphenicol	Loperamide	Secobarbital
Chlorothiazide	Maprotiline	Serotonin (5-Hydroxytyramine)
D,L-Chlolrpheniramine	Meprobamate	Sulfamethazine
Chlorpromazine	Methadone	Sulindac
Chlorquine	Methoxyphenamine	Tetracycline
Cholesterol	(+) 3,4-Methylenedioxyamphetamine	Tetrahydrocortisone, 3 Acetate
Clomipramine	(+)3,4-Methylenedioxymethamphetamine	Tetrahydrocortisone3 (β-Dglucuronide)
Clonidine	Morphine-3-β-Dglucuronide	Tetrahydrozoline
Cocaine hydrochloride	Naloxone	Thebaine
Codeine	Nalidixic acid	Thiamine
Cortisone	Naltrexone	Thioridazine
L-Cotinine	Naproxen	D, L-Thyroxine
Creatinine	Niacinamide	Tolbutamine
Deoxycorticosterone	Nifedipine	Triamterene
Dextromethorphan	Norcodeine	Trifluoperazine
Diazepam	Norethindrone	Trimethoprim
Diclofenac	D-Norpropoxyphene	D, L-Tryptophan
Diflunisal	Noscapine	Tyramine
Digoxin	Oxalic acid	D, L-Tyrosine
Diphenhydramine	Oxazepam	Uric acid
Doxylamine	Oxolinic acid	Verapamil
Ecgonine hydrochloride	Oxycodone	Zomepirac
Ecgonine methylester	Oxymetazoline	

f. Specificity

To test the specificity, drug metabolites and other components that are likely to be present in urine samples were tested. The target drug (Oxycodone or Cannabinoids), its drug metabolites and the related compounds were studied. These samples were tested using three batches of the CR3Keyless Split Sample Cup Oxycodone–Cannabinoids by three different operators. The drug metabolites and other components were tested at different concentrations. The obtained lowest detectable concentration was used to calculate the cross-reactivity. Results are shown in the following tables.

OXY (Oxycodone**, Cut-off=100 ng/mL)**	**Result**	**% Cross-Reactivity**
Oxycodone	Positive at 100 ng/mL	100%
Dihydrocodeine	Positive at 20000 ng/mL	0.5%
Hydrocodone	Positive at 10000 ng/mL	1%
Oxymorphone	Positive at 1000 ng/mL	10%
Codeine	Positive at 100000 ng/mL	0.1%
Hydromorphone	Positive at 100000 ng/mL	0.1%
Morphine	Negative at 100000 ng/mL	Not detected
Acetylmorphine	Negative at 100000 ng/mL	Not detected
Buprenorphine	Negative at 100000 ng/mL	Not detected
Ethylmorphine	Negative at 100000 ng/mL	Not detected
Thebaine	Negative at 100000 ng/mL	Not detected

THC (11-nor-Δ9-THC-9-COOH**, Cut-off=50 ng/mL)**	**Result**	**% Cross-Reactivity**
11-nor-Δ9-THC-9-COOH	Positive at 50 ng/mL	100%
11-nor-Δ8-THC-9-COOH	Positive at 30 ng/mL	167%
11-hydroxy-Δ9-Tetra hydrocannabinol	Positive at 2500 ng/mL	2%
(-)-11-nor-9-carboxy-Δ 9-THC	Positive at 50 ng/mL	100%
11-nor-Δ9-THC-carboxy glucuronide	Positive at 100 ng/mL	50%
Δ8- Tetrahydrocannabinol	Positive at 7500 ng/mL	0.6%
Δ9- Tetrahydrocannabinol	Positive at 10000 ng/mL	0.5%
Cannabinol	Positive at 100000 ng/mL	0.05%
Cannabidiol	Positive at 100000 ng/mL	0.05%

g. Effect of Specific Gravity and Urine pH

Twelve urine samples of normal, high, and low specific gravity ranges (1.000 to 1.035) were collected and spiked with either Oxycodone or Cannabinoids at 25% below and 25% above the corresponding cut-off level. These samples were tested using three batches of the CR3 Keyless Split Sample Cup Oxycodone -Cannabinoids by three different operators.

The pH of an aliquot negative urine pool was adjusted to pH ranges of 4.00 to 9.00 in 1 pH unit increments and spiked with Oxycodone or Cannabinoids at 25% below and 25% above the

corresponding cut-off levels. These samples were tested using three batches of the CR3 Keyless Split Sample Cup Oxycodone -Cannabinoids by three different operators.

The device performance was found not affected by varying specific gravity and pH.

2. Comparison Studies

The method comparison for the CR^3 Keyless Split Sample Cup Oxycodone - Cannabinoids was performed in-house with three laboratory assistants. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were masked and randomized. The obtained test results were compared to GC/MS results. The results are presented in the table below:

Oxycodone

Group / Operators		**Negative**	**Low Negative by GC/MS (less than -50%)**	**Near Cutoff Negative by GC/MS (Between -50% and cutoff)**	**Near Cutoff Positive by GC/MS (Between the cutoff and +50%)**	**High Positive by GC/MS (greater than +50%)**
Viewer A	Positive	0	0	4	18	19
	Negative	10	17	9	3	0
Viewer B	Positive	0	0	3	18	19
	Negative	10	17	10	3	0
Viewer C	Positive	0	0	3	18	19
	Negative	10	17	10	3	0

Discordant table:

Viewer	Sample number	GC/MS result	Viewer result
Viewer A	OXYC1063	95	positive
Viewer A	OXYC1064	98	positive
Viewer A	OXY1218	89	positive
Viewer A	OXY1224	94	positive
Viewer A	OXYC1062	100	negative
Viewer A	OXY1215	102	negative
Viewer A	OXY1221	101	negative
Viewer B	OXYC1063	95	positive
Viewer B	OXYC1064	98	positive
Viewer B	OXY1224	94	positive
Viewer B	OXYC1062	100	negative
Viewer B	OXY1215	102	negative
Viewer B	OXY1221	101	negative

Viewer C	OXYC1063	95	positive
Viewer C	OXYC1064	98	positive
Viewer C	OXY1224	94	positive
Viewer C	OXYC1062	100	negative
Viewer C	OXY1215	102	negative
Viewer C	OXY1221	101	negative

Cannabinoids

Group / **Operators**		**Negative**	**Low Negative by GC/MS (less than -50%)**	**Near Cutoff Negative by GC/MS (Between -50% and cutoff)**	**Near Cutoff Positive by GC/MS (Between the cutoff and +50%)**	**High Positive by GC/MS (greater than +50%)**
Viewer A	Positive	0	0	3	17	20
	Negative	10	10	17	3	0
Viewer B	Positive	0	0	3	16	20
	Negative	10	10	17	4	0
Viewer C	Positive	0	0	4	16	20
	Negative	10	10	16	4	0

Discordant table:

Viewer	Sample number	GC/MS result	Viewer result
Viewer A	THC1206	48	positive
Viewer A	THC1214	49	positive
Viewer A	THC1223	48	positive
Viewer A	THC1220	52	negative
Viewer A	THC1229	51	negative
Viewer A	THC1231	50	negative
Viewer B	THC1206	48	positive
Viewer B	THC1214	49	positive
Viewer B	THC1223	48	positive
Viewer B	THC1219	53	negative
Viewer B	THC1220	52	negative
Viewer B	THC1229	51	negative
Viewer B	THC1231	50	negative
Viewer C	THCC1065	49	positive
Viewer C	THC1206	48	positive
Viewer C	THC1214	49	positive
Viewer C	THC1223	48	positive
Viewer C	THC1219	53	negative

Viewer C	THC1220	52	negative
Viewer C	THC1229	51	negative
Viewer C	THC1231	50	negative

Lay-user study

A lay user study was performed at three intended user sites with 260 lay persons, of which, 20 tested for drug-free samples, 120 for oxycodone samples, 120 for cannabinoids samples. They had diverse educational and professional backgrounds and ranged in age from 21 to >50 years. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cut-off by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers, blind-labeled and randomized. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below:

Cup format		Number of samples	OTC user		%Agreement With GC/MS
Drug	Concentration		Negative	Positive	
Drug -free	-100%	20	20	0	100%
Oxycodone	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%
Cannabinoids	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed A Flesch-Kincaid reading analysis was performed on the package insert and the score revealed a reading grade level of less than 7.

3. Clinical Studies

   Not applicable.

11. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that CR^3 Keyless Split Sample Cup Oxycodone –Cannabinoids is substantially equivalent to the predicate.